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BARND, D EXAMINER

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ART UNIT	PAPER NUMBER
1813	23

DATE MAILED: 08/31/92

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined  Responsive to communication filed on 12/12/91.  This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133.

**Part I --THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1.  Notice of References Cited by Examiner, PTO-892. 2.  Notice re Patent Drawing, PTO-948.  
3.  Notice of Art Cited by Applicant, PTO-1449. 4.  Notice of Informal Patent Application, Form PTO-152  
5.  Information on How to Effect Drawing Changes, PTO-1474. 6.

**Part II --SUMMARY OF ACTION**

1.  Claims 15-22, 36 and 37 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.  
2.  Claims 1-14 and 23-35 have been cancelled.  
3.  Claims \_\_\_\_\_ are allowed.  
4.  Claims 15-22, 36 and 37 are rejected.  
5.  Claims \_\_\_\_\_ are objected to.  
6.  Claims \_\_\_\_\_ are subject to restriction or election requirement.  
7.  This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.  
8.  Formal drawings are required in response to this Office action.  
9.  The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are:  acceptable;  not acceptable (see explanation or Notice re Patent Drawing, PTO-948).  
10.  The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been:  approved by the examiner;  disapproved by the examiner (see explanation).  
11.  The proposed drawing correction, filed \_\_\_\_\_, has been:  approved;  disapproved (see explanation).  
12.  Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has:  been received;  not been received;  been filed in parent application, serial no. \_\_\_\_\_, filed on \_\_\_\_\_.  
13.  Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quigley, 445 C.2d 11, 433 O.G. 213.  
14.  Other \_\_\_\_\_

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15. Applicant's cancellation of claims 1-14, 23, 25, 27 and 29-35 in Paper No. 22 is acknowledged. Claims 15-22 and new claims 36 and 37 are pending.

16. The text of those sections of 35 U.S. Code not included in this office action can be found in the prior office action.

17. The prior rejection of claims 15-22 based on lack of utility is maintained. Applicant's arguments have been fully considered but they are not deemed to be persuasive. No evidence has been provided that the disclosed method can be used to immunize against a human cellular oncogene product. Applicant argues that, because they have shown that the immune system can modulate a tumor, they have thus established utility and enablement. However, Applicant has only demonstrated rejection by a mouse of a tumor expressing the rat neu gene product, which for reasons stated in the prior office action, appears to result from recognition by mice of xenotypic determinants on the rat protein. For reasons also of record, these results do not imply that one can immunize against a human cellular oncogene product by immunization with a recombinant poxvirus expressing such an oncogene or expressing the rat "homologue" of such an oncogene. Claims 15-22, 36 and 37 are rejected under 35 U.S.C. 101 for the reasons set forth supra.

18. The prior rejection of claims 15-22 under 35 U.S.C. 112, first paragraph, based on lack of an enabling disclosure is maintained. Applicant's arguments have been fully considered but they are not deemed to be persuasive. The specification is not enabled for the claimed method of immunization for the reasons stated in the prior office action. For example, the specification is not enabled for the use of the claimed method because the utility of the invention has not been proven (see

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rejection under 35 U.S.C. 101 above). Further, the specification is not enabled for a recombinant poxvirus vector comprising other than the neu oncogene, or comprising immunogenic portions of oncogene or proto-oncogene products. Claims 15-22, 36 and 37 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth supra.

19. Claims 15-22, 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 15-22, 36 and 37 are indefinite in their use of the term "cellular oncogene...or a homologous oncogene or proto-oncogene" because it is unclear how such a "homologous" oncogene or proto-oncogene is defined (i.e. do such "homologs" have a defined percent nucleotide sequence identity, do such "homologs" encode proteins having a similar defined function?).

20. The prior rejection of claims 15-22 under 35 U.S.C. 103 as unpatentable over Lathe et al. in view of Padhy et al., further in view of Yamamoto et al., is maintained. Applicant's arguments have been fully considered but they are not deemed to be persuasive. Applicant argues that Lathe et al. is directed to a method of immunizing an animal with a recombinant vaccinia virus (VV) expressing antigens of polyoma virus (rather than an oncogene) and that there is nothing in Padhy et al. or Yamamoto et al. that teach or suggest the substitution of an oncogene for the polyoma virus antigen in the recombinant VV of Lathe et al., and the use of such a recombinant VV in the immunization against oncogene-expressing tumors. However, because the oncogene, like the polyoma virus antigen, is a transformation-specific antigen, it is maintained that it would have been obvious to one of ordinary skill in the art to substitute the transformation-specific antigen taught by Padhy et al. or Yamamoto et al. for

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the transformation-specific antigen in the recombinant VV taught by Lathe et al., and to use such a recombinant VV for immunization purposes as also taught by Lathe et al., for the expected result of eliciting a tumor-specific immune response (i.e. an immune response in mice specific for rat neu oncogene-expressing tumors).

21. Applicant's amendment necessitated the new grounds of rejection. Accordingly, THIS ACTION IS MADE FINAL. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

22. Papers relating to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 196 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4227.

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23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna L. Barnd whose telephone number is (703) 308-3908. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

August 24, 1992

Donna L. Barnd, Ph.D.

  
CHRISTINE M. NUCKER  
SUPERVISORY PATENT EXAMINER  
GROUP 180